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The Effects of Isolated Telephone Interventions on Glycemic Control in Type 2 Diabetes

A Literature Review

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A systematic literature review of studies published between 1990 and 2008 was conducted to evaluate the impact of isolated telephone interventions on glycemic control in adults with type 2 diabetes. Eight randomized controlled trials met the inclusion criteria. Overall, the interventions had mixed effects on glycemic control, suggesting further research is needed in this area. Current evidence does not support isolated telephone interventions to improve glycemic control in type 2 diabetes mellitus; well-designed studies to establish the effectiveness of this potentially cost-effective modality can be an important step in addressing the diabetes epidemic. **Key words:** *diabetes*, *type 2*, *disease management*, *glycemic control*, *HbA$_{1c}$*, *literature review*, *telephone intervention*

BACKGROUND AND SIGNIFICANCE

Diabetes mellitus (DM) is a group of metabolic disorders resulting from disturbances in both insulin production and utilization, leading to hyperglycemia. It is a growing public health problem that is an epidemic in the United States. An estimated 23.6 million Americans have DM, and approximately 1.5 million new cases are diagnosed each year.[1] Diabetes is the nation's sixth leading cause of death by disease, contributing to more than 200 000 deaths annually.[2] Type 2 DM, the most prevalent type, accounts for 90% to 95% of all DM cases.[3] Previously thought to be a less severe form of DM, clinical studies have shown that uncontrolled hyperglycemia in type 2 DM results in the same long-term vascular complications as seen in type 1 DM.[4] The United Kingdom Prospective Diabetes Study (UKPDS), a 10-year landmark study involving 3867 patients with type 2 DM, demonstrated overwhelmingly that intensive therapy aimed at achieving even modest improvements in hemoglobin A_{1c} (HbA_{1c} levels) plays an essential role in reducing the risk of developing microvascular complications (eg, retinopathy, neuropathy, and nephropathy) and in fostering trends toward reductions in myocardial infarction and stroke.[5,6]

Despite important advances in the management of type 2 DM, informed by seminal studies such as the UKPDS and disseminated in numerous practice guidelines, overall glycemic control has not improved and has worsened in patients with type 2 DM.[7] After examining data from 1587 participants in 2 large representative national surveys (ie, the National Health and Nutrition Examination

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Survey III [1988–1994] and National Health and Nutrition Examination Survey [1999–2000]) Koro and colleagues[7] observed that, consistent with current recommendations toward earlier and more aggressive treatment in type 2 DM, more patients were being treated with oral hypoglycemic agents and oral agents and insulin combined. The authors also reported, however, that the rate of adequately controlled type 2 DM in adults, defined as HbA_{1c} values less than 7.0%, decreased significantly between the time periods 1988 to 1994 and 1999 to 2000, from 45% to 36%, respectively.

In another study examining the National Health and Nutrition Examination Survey data, Harris[8] examined the relationship between medical care, health status, and outcomes of 733 adults with type 2 DM from the National Health and Nutrition Examination Survey III. The author reported that, in patients who reported good access to medical care (95% indicating they had 1 usual source of ambulatory medical care, 88% reporting having had 2 or more physician visits in the past 12 months, and 91% indicating that they had health insurance), at least 58% had HbA_{1c} values over 7.0%.

Problem statement

It is well established that intensive treatment in type 2 DM is needed to achieve adequate glycemic control to prevent complications and that access to and utilization of medical care is not sufficient to help patients achieve satisfactory glycemic targets.

Telephone technology

The telephone is an easy-to-use familiar technology that is almost universally available in the United States. Data from a randomly selected national sample of approximately 32 000 households in 2004 show that 94.6% of the households had a telephone (46.4% landline and cell, 42.2% landline only, 6% cell only).[9] Studies of primary interventions involving the telephone have been shown to improve adherence to medications and to improve blood pressure readings in patients with hypertension, to improve quality of life in patients with cardiac problems, and to be effective in changing physical activity and dietary behaviors.[10–12] Riegel and colleagues[13] showed that a telephone intervention reduced hospitalizations and overall costs in patients with heart failure compared with other disease management approaches. Extensive telephone access to healthcare practitioners was a key element found to maintain lower HbA_{1c} levels in the Diabetes Control and Complications Trial involving patients with type 1 DM.[14]

Understanding the effects of telephone-based interventions in type 2 DM is important because providing care for these individuals is resource intensive, which drives up the cost of care. The estimated direct medical costs for treatment of diabetes and its complications in the United States was $92 billion in 2002. Medical costs for populations with DM are estimated to be 2.4 times higher than for populations without diabetes.[15] Considering the increasing incidence of type 2 DM, its accounting for an overwhelming percentage of all DM cases, and the scarcity of healthcare resources, the challenge for healthcare providers is to apply evidence-based recommendations of cost-effective, easily implemented interventions that have the potential to assist large numbers of patients with type 2 DM to improve glycemic control.

PURPOSE STATEMENT

The purpose of this systematic literature review was to perform a comprehensive review of relevant quantitative studies on the impact of telephone interventions on glycemic control in adult patients with type 2 DM. The availability of the telephone and its familiarity make it an ideal method for communicating with patients with type 2 DM between clinic visits. Understanding the evidence regarding telephone-based interventions in type 2 DM will inform providers caring for these patients

and for patients with other chronic conditions and assist them in making decisions as to the merits of implementing telephone interventions in their practice.

METHODS

Data sources

The search was conducted using EBSCOhost research databases. The databases Academic Search Premier, ClinicalTrials.gov, CINAHL (Cumulative Index to Nursing and Allied Health Literature), The Cochrane Database of Systematic Reviews, MEDLINE, PsychINFO, and psychARTICLES were searched using the search terms tele* and (DM or type 2 diabetes) and (glycemic control or HbA_{1c} or self-monitoring of blood glucose) and adult. The asterisk represented the system's truncation symbol that allowed variations of search terms to be searched. Limits included studies published in peer-reviewed journals in the English language and the publication years 1990 through 2008. Studies published prior to 1990 were excluded because data supporting the relationship between tight glycemic control and chronic complications of DM were limited prior to that time.[14]

Selection

Study selection criteria included original quantitative studies published in English evaluating the impact of a telephone intervention on glycemic control measured by HbA_{1c} levels. Samples included adult patients with type 2 DM either using or not using exogenous insulin. All titles and abstracts were reviewed for relevance, and those meeting the study selection criteria were retrieved along with articles in which a determination of relevance could not be made by reviewing the titles and abstracts. Reference lists of retrieved articles were screened for additional relevant studies. Seventy initial titles and abstracts were reviewed; the selection process resulted in 8 published randomized controlled trials (RCTs) selected for this review.

The Cochrane Database search resulted in 4 documents of interest, 2 future protocols[16,17] and 2 published reviews.[18,19] The 2 protocols described processes to be used in future reviews, one involving telephone follow-up in patients with type 2 DM,[16] and another review of mobile phone messaging involving patients with both type 1 and type 2 DM.[17] The 2 reviews were of (*a*) interventions for improving adherence to treatment recommendations in patients with type 2 DM[18] and (*b*) interventions to improve management of both type 1 and type 2 DM in outpatient settings.[19] Only 4 studies in these 2 reviews included telephone interventions, and 3 of these studies were excluded from this review. One study was excluded because it required participants to access the Internet, 1 study focused on a multifactorial intervention, and another included only children with DM. The fourth study was a duplicate study found during the initial search and was included in this review.

Studies other than RCTs were considered for inclusion in this review. However, no prospective cohort studies or case-control studies were retrieved after reviewing the titles and abstracts. This is not surprising since studies evaluating the effects of telephone interventions on glycemic control lend themselves to an RCT design by the nature of the research questions being asked.

Studies that required patients to either have home access to the Internet or travel to a site where the Internet was available were excluded from the review because although this technology is becoming more widely available in the homes of individuals, it is not as widely available as the telephone. According to the United States Census Bureau,[20] only 54.7% of households reported Internet access in 2003.

Validity assessment and grading system

Internal validity of the studies was determined according to 6 domains of the Cochrane methodology[21] using The Cochrane Collaboration's tool for assessing risk of bias. Using this method, the authors

judged the studies separately on the basis of what was reported in the articles in relation to the 6 domains. Discrepancies were discussed, and consensus in judgment was achieved. A judgment of "no" indicated a high risk of bias in that domain, a judgment of "unclear" indicated an uncertain risk of bias, and a judgment of "yes" indicated a low risk of bias in that domain. The overall body of evidence for the RCTs evaluated in this systematic review was rated according to the American Diabetes Association[22] grading system. The American Diabetes Association grading system describes an overall level of evidence for a body of literature according to published criteria. A rating of "A" indicates that there is "Clear evidence from well-conducted, generalizable, RCTs."[22(pS5)] A rating of "B" indicates that there is "Supportive evidence from well-conducted cohort studies."[22(pS5)] A rating of "C" indicates that there is "Supportive evidence from poorly controlled or uncontrolled studies"[22(pS5)]; and a rating of "D" indicates that there is "Expert consensus or clinical experience."[22(pS5)]

Data abstraction and study characteristics

The data were collected and organized into a table to assist with comparisons across studies using a Review Matrix described by Garrard.[23] Data were collated according to the purpose of the study, the intervention, the design and sample, the outcome measures, the measurement instruments, and the results (Table 1).

RESULTS

Purpose

The main purpose of 6 of the studies reviewed was to evaluate the effect of a telephone-delivered intervention on glycemic control in patients with type 2 DM.[25,26,28–31] Two studies evaluated the effects of a telephone component of a broader program on glycemic control in patients with type 2 DM.[24,27]

Interventions

The interventions consisted primarily of outgoing calls to patients. Young et al[31] was the only study that reported incoming calls from patients (10% of telephone consultations). Seven of the 8 interventions reviewed consisted of tailored messages based on either an initial assessment or ongoing assessments based on participants' responses to queries.[24–26,28–31] Maljanian et al[27] delivered scripted messages intended to reinforce education and self-management skills presented to participants at an initial education session. The authors of this study did not report an initial or ongoing assessment of participants on which the script was tailored.

Glasgow and Toobert[24] conducted a baseline interactive multimedia computer-assisted dietary assessment that resulted in a tailored dietary fat reduction goal based on participants' eating patterns and preferences. The follow-up calls provided ongoing support, reinforcement, and problem solving aimed at attaining these goals. The interventions in 3 studies provided education and reinforcement of self-care activities and provided dietary and medication adjustment recommendations on the basis of information obtained from participants' glucose, diet, and exercise logs kept during the intervention.[25,26,28]

The interventions in the 2 studies by Piette and colleagues[29,30] consisted of automated technology that delivered messages in a human voice and that gathered information via touch-tone or voice-recognition technology aimed at determining participants' health status. Based on reports generated weekly, nurses contacted participants to address problems reported during the automated assessments and provided more self-care education. Primary care physicians were contacted if the acuity of the call warranted a contact. The intervention in the study conducted by Young et al[31] consisted of starting with a series of questions generated from a call center using an intranet protocol to identify gaps in knowledge and providing advice regarding lifestyle improvements. Subsequent components of the intervention consisted of

Table 1. Study characteristics

Authors, year, and research objective	Telephone and control conditions	Design and sample	Outcome measures and measurement instruments	Effects of interventions
Glasgow and Toobert[24] Evaluate the effectiveness, adoption, and implementation of a brief behavioral dietary intervention (basic condition) and 2 supplemental components of DM self-management support: TF calls and CR enhancement	Brief structured telephone calls to provide • Support, reinforcement of diabetes education, tailored dietary counseling, problem solving • 3–4 calls during 6 mo (implementation scores 80%–90%) • Duration of intervention 6 mo • Endpoint assessment 6 mo Control group received general pamphlet on low-fat eating	RCT • Random assignment to 1 of 4 groups (basic condition, basic condition and TF, basic condition and CR, combined) • Type 2 DM • Average age 59 yr • 56% female • 90% white • 57% attended at least some college • $N = 320$, attrition 8.5% at 3 mo, 13.4% at 6 mo • No report of sample size analysis	• GC determined by HbA_{1c} levels • Behavioral outcomes assessed by the Kristal Fat and Fiber Behavior Scale, good psychometric properties • Total cholesterol, weight, lipid ratio • QOL measured via the IIS, good psychometric properties • Patient satisfaction measured via an instrument adapted by the researchers (the Cronbach $\alpha = .86$)	• Small NS overall reduction in HbA_{1c} levels (0.1–0.2 percentage points) • Significant difference favoring TF conditions on the Kristal Fat and Fiber Behavior Scale ($P = .017$) • NS reduction in total cholesterol and lipid ratios ($P = .10$) across conditions • Little change in illness-related QOL • No main effects on the IIS or on patient satisfaction • Adding TF did not enhance outcomes beyond basic intervention
Kim and Oh[25] To investigate the effect of nurse telephone calls on HbA_{1c} levels and adherence to diabetes control recommendations	Counseling regarding • Maintaining BG within near-normal range, diet, exercise, medication adjustment, SMBG • Calls twice a week for the first month, once a week for the second and third months (average of 16 telephone calls per participant) • Duration of intervention 3 mo • Endpoint assessment 3 mo Control group: visiting physician every 3 mo	RCT • Random assignment to telephone or control group • Type 2 DM, $HbA_{1c} \geq 7\%$ • Average age 60 yr • 70% female • 100% Korean[a] • 50% completed more than high school • $N = 50$, attrition 28% • No report of sample size analysis	• GC determined by HbA_{1c} levels • Diabetes adherence measured by a self-reported questionnaire developed by the researchers that included 20 items measured by a VAS, good psychometric properties	• Significant decrease in mean change in HbA_{1c} levels between groups (−1.2 vs +0.6 percentage points, $P < .05$) • Significant interaction between diet ($P = .006$) and SMBG adherence ($P = .024$) between groups and times • NS interaction between exercise, medication-taking, low BG management and foot care adherence between groups and times

(*continues*)

Table 1. Study characteristics (*Continued*)

Authors, year, and research objective	Telephone and control conditions	Design and sample	Outcome measures and measurement instruments	Effects of interventions
Kim et al[26] To evaluate the effect of a nurse-coordinated intervention to improve GC, blood lipids, and patient satisfaction with care in nonobese patients with type 2 DM	Counseling regarding • Maintaining BG within near-normal range, diet, exercise, medication adjustment, SMBG • Calls twice a week for the first month, once a week for the second and third months (average of 16 telephone calls per participant) • Duration of intervention 3 mo • Endpoint assessment 3 mo Control group: visiting physician every 3 mo	RCT • Random assignment to telephone or control group • Type 2 DM, $HbA_{1c} \geq 7\%$ • Average age 60.5 yr • 65% female • 100% Korean[a] • 55% completed more than high school • $N = 35$, attrition 29% • For an effect size of 0.7 at a power of 0.8 and an α of .05, 33 participants needed per group	• GC determined by HbA_{1c} levels, FBG, and 2-hour postprandial glucose levels • Triglycerides and HDLC levels • Patient satisfaction with care measured via a VAS with zero indicating no satisfaction and 10 indicating much satisfaction	• Significant decrease in mean change in HbA_{1c} levels (-1.2 in intervention group and $+0.5$ percentage points in control group, $P = .004$). • NS changes in FBS, 2-hour postprandial glucose, triglyceride, or HDLC between groups • Satisfaction with care significance higher in the intervention group ($P = .023$)
Maljanian et al[27] To evaluate the value of an intensive TF as an additional component of diabetes disease management program already shown to be effective in improving GC, adherence with ADA standards of care, and HRQOL	Weekly phone calls to • Reinforce education and self-management skills • Number of calls received not reported • Duration of intervention 3 mo • Endpoint assessment 3 and 12 mo Control group received routine care consisting of visiting physician every 3 mo	RCT • Random assignment to telephone or control group *assumed* • 96% type 2 DM • Average age 58 yr • 53% female • 70% white • Education not reported • $N = 507$, attrition 34% • No report of sample size analysis	• GC determined by HbA_{1c} levels • HRQOL measured by Short Form 36 • Disease-specific QOL and patient satisfaction measured by Diabetes Specific Quality of Life Questionnaire developed as part of the DQIP • Depression measured by Epidemiologic Studies Depression Scale • Adherence to self-management guidelines measured by DQIP • Psychometric properties not reported, but references provided	• Group assignment was not a significant predictor of whether participants met ADA target of <7.0% for HbA_{1c} levels at 3- or 12-mo follow-up • No significant differences between telephone and control group on GC or any of the measures of general or specific HRQOL, symptoms of depression, or patient satisfaction at either 3 or 12 mo • Adherence to ADA standards of care was significantly better with the added telephone intervention

(*continues*)

Table 1. Study characteristics (*Continued*)

Authors, year, and research objective	Telephone and control conditions	Design and sample	Outcome measures and measurement instruments	Effects of interventions
Oh et al[28] To investigate the effect of a telephone-delivered intervention on GC and BMI in Korean patients with type 2 DM	Counseling regarding • Maintaining BG within near-normal range, diet, exercise, medication adjustment, SMBG • Calls twice a week for the first month, once a week for the second and third months (average of 16 telephone calls per participant) • Duration of intervention 3 mo • Endpoint assessment 3 mo Control group: visiting physician every 3 mo	RCT • Random assignment to telephone or control group • Type 2 DM • Average age 60 yr • 65% female • 100% Korean[a] • 54% completed more than high school • $N = 50$, attrition 24% • No report of sample size analysis	• GC determined by HbA_{1c}, levels FBG, and 2-hour postprandial glucose • BMI	• Significant decrease in mean change in HbA_{1c} levels (-1.2 percentage point change in HbA_{1c} levels in intervention group compared to a $+0.3$ percentage point change in HbA_{1c} levels in control group, $P = .000$) • No significant difference between groups in mean FBG or 2-hour post-prandial glucose levels • No significant differences between groups in BMI
Piette et al[29] To evaluate automated telephone disease management with telephone nurse follow-up as a strategy for improving diabetes treatment process and outcomes in the Department of Veterans Affairs clinics	Biweekly automated telephone assessments to • Identify patients with health and self-care problems, focus efforts of nurse educator on patients with the greatest problems, deliver targeted and tailored self-care messages • Mean 13 contacts per patient, 3.8 hours contact time • Duration of intervention 12 mo • Endpoint assessment 12 mo Control group: no information	RCT • Random assignment to telephone or control group • Type 1 and type 2 DM • Average age 60.5 yr • 3% female • 60% white • 21% annual income • <$10 000 per year • $N = 272$, attrition 7% • No report of sample size analysis	• GC determined by HbA_{1c} levels and serum glucose levels • Satisfaction with care measured using the Employee Healthcare Value Survey • No psychometric properties of satisfaction scale reported, but reference provided	• NS difference on mean HbA_{1c} levels ($P = .3$). Patients with baseline $HbA_{1c} \geq 8\%$, adjusted mean endpoint HbA_{1c} values differed by 0.5 percentage points ($P = .04$) and by 1.1 percentage points for baseline $HbA_{1c} \geq 9$ ($P = .04$) • Intervention patients reported more frequent SMBG and foot inspections ($P = .05$), had more podiatry visits ($P = .003$), diabetes visits ($P = .03$), cholesterol tests ($P = .05$), and reported fewer symptoms of poor GC ($P = .04$)

(*continues*)

Table 1. Study characteristics (*Continued*)

Authors, year, and research objective	Telephone and control conditions	Design and sample	Outcome measures and measurement instruments	Effects of interventions
Piette et al[30] To evaluate the effect of automated telephone assessment and self-care education calls with nurse follow-up on the management of diabetes	Biweekly automated telephone assessments to • Patients with health and self-care problems, focus efforts of nurse educator on patients experiencing the greatest problems, deliver targeted and tailored self-care messages • Mean 6 contacts per patient, 1.2 hour contact time • Duration of intervention 12 mo • Endpoint assessment 12 mo Control group: no systematic monitoring between clinic visits	RCT • Random assignment to telephone or control group • Type 1 and type 2 DM • Average age 54.5 yr • 59% female • 30% white, 50% Hispanic • 58% annual income <$10 000 per year • $N = 280$, attrition 11% • No report of sample size analysis	• GC determined by HbA_{1c} levels, and serum glucose levels • Frequency of glucose monitoring, foot inspection, and weight monitoring measured by participants ratings on a 5-point Likert scale psychometrics not provided • Perceived GC measured by participant ratings on a 5-point Likert scale psychometrics not provided • BMI • Healthcare utilization	• No significant difference on mean HbA_{1c} levels ($P = .1$) • Intervention increased the proportion of patients with normal HbA_{1c} levels by 9% ($P = .04$), decreased serum glucose levels by 41 mg/dL ($P = .002$), and improved self-reported GC ($P = .005$) • Significant improvement in frequency of glucose monitoring ($P = .03$), foot inspection ($P = .02$), weight monitoring ($P = .001$), and decrease in reported medication problems ($P = .003$)
Young et al[31] To determine whether PACCTS, using trained nonmedical telephonists supported by specially designed software and a diabetes nurse, can effectively improve GC in type 2 DM	Protocol-based calls regarding • Knowledge of DM, readiness for change, medication adherence, SMBG • Frequency varied by • Number of calls per participant not reported • Duration of intervention 12 mo • Endpoint assessment 12 mo Control group managed according to same guidelines	RCT • Participants randomly selected • Random assignment stratified by baseline HbA_{1c} levels (<7%, 7%–9%, or >9%) • Type 2 DM • Average age 67 yr • 41.2% female • Sample drawn from 95% white European population; 80% lowest socioeconomic status category • $N = 591$, 14% attrition • Sample size analysis based on mean difference between groups of >1% reduction in HbA_{1c} levels, significance level .05, power 90%	• GC determined by HbA_{1c} levels	• Significant improvement in HbA_{1c} levels of 0.3 percentage points in the PACCTS ($P = .003$). Patients with baseline HbA_{1c} levels of 7%–9%, significant improvement in HbA_{1c} levels of 0.49 percentage points ($P = <.001$) • A 10% increase in those achieving a 1 percentage point reduction of HbA_{1c} level was seen in the telephone group ($P < .001$)

Abbreviations: ADA, American Diabetes Association; BG, blood glucose; BMI, body mass index; CR, community resources; DM, diabetes mellitus; DQIP, Diabetes Quality Improvement Project; FBG, fasting blood glucose; FBS, fasting blood sugar; GC, glycemic control; HbA_{1c}, hemoglobin A_{1c}; HDLC, high-density lipoprotein cholesterol; HRQOL, health-related quality of life; IIS, Illness Intrusiveness Scale; NS, nonsignificant; PACCTS, Pro-active Call Center Treatment Support; QOL, quality of life; RCT, randomized controlled trial; SMBG, self-monitoring blood glucose; TF, telephone follow-up; VAS, visual analog scale.

[a]Presumed 100% Korean sample.

assessing and supporting readiness to change, and assessment of medication adherence and glucose control. Information gathered from participants was subject to review, and referrals were made to diabetes specialist nurses who were able to adjust medications according to established guidelines.

Duration of the interventions varied from 3 months[25–28] to 12 months.[24,29,30,31] The duration of the intervention in the study conducted by Glasgow and Toobert[24] was 6 months. Outcomes were measured immediately after the interventions ceased in all studies except Maljanian et al,[27] where outcomes were assessed immediately after the 3-month intervention and again at 12 months.

Nurses were involved in all of the interventions either by directly making the calls,[24–28] by supervising calls made by trained telecarers,[31] or by conducting follow-up calls in response to participants' reports from automated assessments.[29,30] None of the studies mentioned the use of cellular phones in the intervention.

Design and validity assessment

All of the studies reported using a randomized controlled design. Details regarding the randomization methods and concealment of allocation were lacking in some of the studies. In 2 studies,[25,28] the authors reported randomization by the toss of a coin to either intervention or control groups. The authors did not explain how equal numbers in each group were obtained or whether allocation concealment was done. Another study described randomization using a random number table; allocation concealment was not reported.[26] The 2 studies by Piette and colleagues[29,30] reported both sequence generation (ie, randomization using a table of randomly permuted numbers) and allocation concealment (ie, sealed envelopes prior to randomization). Young et al[31] was the only study to report random selection of participants from a sampling frame generated from a list of individuals with type 2 DM. The authors also reported sequence generation (ie, postrecruitment block randomization stratified by HbA_{1c}); allocation concealment was reported, but not fully described. The 2 remaining studies[24,27] reported insufficient detail regarding random assignment and did not report allocation concealment.

With the exception of 2 studies that reported analysis of HbA_{1c} in a blinded fashion by laboratory personnel who were not aware of group allocation,[29,30] blinding was not addressed in the studies. Incomplete outcome data were addressed in all of the studies reviewed with attrition rates between 7% and 34%. Four studies[24,29–31] were given a judgment of "yes" indicating that in the reviewers' judgment adequate measures were taken to control for this bias. Two studies[25,28] were given a judgment of "unclear" because information regarding differences between individuals who stayed in the study compared with those who dropped out was not provided. One study had a high (34%) attrition rate[27] and another study had an imbalance in missing outcome data between groups.[25]

All 8 studies appeared to be free of bias related to selective outcome reporting, and the majority of the studies contained no obvious other sources of bias. However, 2 studies[25,28] may have recruited participants from the same institution during overlapping periods of time. It was unclear whether these 2 samples were independent of each other.

Samples and settings

Samples ranged in size from 35 to 591. A sample size analysis was reported in 2 studies.[26,31] Five of the studies included patients with type 2 DM only.[24–26,28,31] Ninety-six percent of the participants in the study by Maljanian et al[27] had type 2 DM. Two studies[29,30] did not specify the type of DM; however, since 90%–95% of individuals with diabetes have type 2 DM, and less than 40% of the participants in these samples were taking insulin, one can surmise that the majority of the participants in these 2 studies had type 2 DM.

Three of the studies[25,26,28] recruited small samples of predominately female,

educated participants from an endocrinology outpatient department of a tertiary care hospital in an urban city in South Korea, which limits generalizability to similar individuals at a similar setting. These studies also excluded patients with severe cardiovascular disease or uncontrolled hypertension, which further limits generalizability. One study[31] recruited participants from a primarily white, low-socioeconomic inner-city location in Greater Manchester, England, from a number of general practices. The fact that a number of general practices were included in the study enhances external validity, but generalizability is still limited to a similar group of white individuals who reside in a low-socioeconomic urban area in England. One study[30] recruited participants from 2 general medicine clinics of a county public health system in California. Their sample was 50% Hispanic, with the majority of participants earning $10 000 or less per year. This study was replicated in a Veterans Affairs healthcare system; this sample[29] consisted of mostly male participants, with a race mix of white, black and Hispanic participants who were better-off at baseline in terms of socioeconomic status, self-care, and glycemic control compared with the county cohort. Intervention effects were observed in both studies, but to a lesser extent in the Veterans Affairs study. The replication study showing intervention effects in the same direction as the original study and the diversity of participants and settings in these 2 studies enhances the external validity of these 2 studies. Another study[27] recruited participants from a hospital-based DM clinic in Connecticut. This sample was made up of primarily middle-aged and white participants. One study[24] increased the external validity of their sample by recruiting from 12 primary care small group practices that had privileges at a community hospital in Oregon. The participants were primarily white, and more than half reported having attended at least some college.

The average age across studies was similar, mean = 60 years (range 54.5–60.5). With the exception of the study conducted at a Veterans Affairs medical center,[29] close to 60% of the participants in the studies were women, mean 57% (range 42%–70%). Of the 7 studies reporting insulin use, on average approximately 34% of participants were using insulin (range 16%–48%).

Glycemic control outcomes

Glycemic control was determined by HbA_{1c} levels in all of the studies either by comparing the mean change in HbA_{1c} levels between intervention and control groups or by comparing mean endpoint HbA_{1c} levels between the 2 groups. Using analysis of covariance to adjust for baseline values and use of insulin, Glasgow and Toobert[24] analyzed 267 participants who had follow-up HbA_{1c} data at both 3 and 6 months. The researchers found no statistically significant differences among the 3 treatment groups in mean change in HbA_{1c} levels at either endpoint; a small overall mean reduction of 0.1 percentage points to 0.2 percentage points was seen (P = ns).

Using analysis of variance, Kim and Oh[25] analyzed 36 participants who had follow-up data at 3 months and found a statistically significant decrease in mean change in HbA_{1c} levels between the treatment and control groups (−1.2 percentage points in the intervention group and +0.6 percentage points in the control group, $P < .05$). Similarly, in the study reported by Kim et al[26] using analysis of variance, the authors analyzed 25 participants who had follow-up data at 3 months and found a statistically significant decrease in mean change in HbA_{1c} levels (−1.2 percentage points in the intervention group and +0.5 percentage points in the control group, $P = .004$). Oh et al[28] reported a statistically significant mean change in HbA_{1c} levels in 38 participants completing a 3-month study; the analysis of variance showed a −1.2 percentage point change in HbA_{1c} levels in the intervention group compared with a +0.3 percentage point change in HbA_{1c} levels in the control group ($P = .000$).[28] The authors of these 3 studies did not report adjusted analyses, but noted that there was no statistically significant difference

in baseline HbA_{1c} levels between intervention and control groups.

In the study by Young et al,[31] mean differences in HbA_{1c} levels in 394 intervention participants and 197 control participants at 12 months were analyzed by baseline HbA_{1c} strata. Overall, a statistically significant improvement in mean change in HbA_{1c} levels of 0.3 percentage points was seen in the intervention group when compared with the control group ($P = .003$). For participants with a baseline HbA_{1c} level of 7% or more, the improvement increased by 0.49 percentage points ($P < .001$); participants with a baseline HbA_{1c} level less than 7% experienced no change. No changes were found to be due to age, gender, or practice type.

When adjusting for baseline values and use of insulin, Piette et al[30] found no statistically significant differences between the treatment and control groups' mean endpoint HbA_{1c} levels measured at 12 months (8.4% intervention group vs 8.1% control group, $P = .1$) in their analysis of 248 participants. A statistically significant proportion of participants was found to have a normal HbA_{1c} level defined as less than 6.4%, in the intervention group compared with the control group at the end of the study (8% normal in the control group compared with 17% normal in the intervention group, $P = .04$). Similarly, in their replication study,[29] the overall adjusted endpoint mean HbA_{1c} levels at 12 months in 272 participants providing data was nonsignificant (8.1% intervention group vs 8.2% control group, $P = .3$). However, when the analysis was restricted to participants with a baseline HbA_{1c} level of 8% or more ($n = 122$), adjusted mean endpoint HbA_{1c} levels values differed by 0.5 percentage points between intervention and control groups ($P = .04$). Among participants whose baseline HbA_{1c} level was 9% or more, adjusted mean endpoint values differed by 1.1 percentage points ($P = .04$).

Maljanian et al[27] reported on 274 participants at 3 and 12 months. There was no statistically significant difference between intervention and control participants on adjusted analysis of mean endpoint HbA_{1c} levels (P value not reported). Group assignment was not a significant predictor of whether the participant met the American Diabetes Association target of less than 7.0% for HbA_{1c} levels at the 3- or 12-month follow-up point. The authors speculated that an overall decrease in HbA_{1c} levels to a mean of 6.8% may have reached a floor effect with the successful base program, and that without the base program, the telephone intervention may have had a more pronounced effect on glycemic control.

SYNTHESIS

The aim of this review was to perform a comprehensive review of relevant quantitative studies on the impact of telephone interventions on glycemic control in adult patients with type 2 DM. A moderate number of studies were initially identified, but only 8 met the final inclusion criteria. These 8 studies were heterogeneous in terms of the populations studied, the settings, the type and intensity of the interventions, the outcomes assessed, and study quality.

Effectiveness of interventions on glycemic control

Overall, the interventions in the studies had mixed effects on glycemic control in adult patients with type 2 DM. In the UKPDS[5] for each reduction in mean HbA_{1c} levels of 1 percentage point, a reduction in risk of 37% was realized for microvascular complications, 14% for myocardial infarction, and 21% for deaths, ($P = .0001$). The studies in this review that evaluated interventions of a shorter duration (ie, 3 months) showed changes in HbA_{1c} levels that are thought to be clinically relevant: a mean change in HbA_{1c} levels of -1.2 percentage points in the intervention groups compared with mean change in HbA_{1c} levels of $+0.6$ percentage points, $+0.5$ percentage points, $+0.3$ percentage points, respectively in the control groups.[25,26,28] The other study that demonstrated a statistically significant difference between intervention and control groups on change in HbA_{1c} level was of questionable clinical significance (-0.3

percentage points); the intervention duration was 12 months.[31]

Four studies[24,27,29,30] did not show positive effects on glycemic control when comparing entire cohorts of intervention with control groups. In one study[24] the primary focus was a dietary intervention aimed at improving behavioral, physiological, quality of life, and satisfaction outcomes. The intervention was moderately successful at achieving self-reported dietary improvements. Maljanian and colleagues[27] demonstrated a reduction in HbA_{1c} level with an initial hospital-based disease management model. However, no further reductions in HbA_{1c} level were seen when the telephone component was added, perhaps due to a floor effect. The 2 studies by Piette and colleagues[29,30] did not show statistically significant differences between groups on mean HbA_{1c} level at the end of their 12-month interventions. They did observe some differences when dividing groups into cohorts of participants with HbA_{1c} levels of less than 6.4% and of 8.0% or more.[29,30]

Internal validity

The overall "grade," based on the American Diabetes Association grading system assigned by these authors to this body of evidence, evaluating the use of telephone interventions on glycemic control in patients with type 2 DM is a Level of Evidence "C," meaning that there is "evidence from RCTs with 1 or more major or 3 or more minor methodological flaws that could invalidate the results."[22(pS5)] Despite fairly large sample sizes in 5 studies, only 2 reported a sample size analysis,[26,31] which limits the ability to determine if the studies were adequately powered *a priori* based on a theoretically determined effect size. Only 2 studies[29,30] adequately reported allocation concealment. Lack of allocation concealment can lead to bias that undermines the theoretical benefits of random assignment. Studies have shown that lack of allocation concealment can lead to exaggerated treatment effects.[32]

Control conditions were mentioned in all but 1 study,[29] but sufficient detail regarding control conditions was lacking across studies, making it difficult to judge whether conditions other than exposure to the intervention were responsible for observed outcomes. Only 1 study[31] reported comparing changes in medication between treatment and control groups that occurred during the intervention period, and only 3 studies compared diabetes-related healthcare visits between intervention and control groups during the intervention period.[27,29,30] Theoretically, large samples and random assignment of participants to intervention and control groups should control for these potentially confounding variables, but because of their strong potential effect on outcomes, reporting on the balance of medication changes and interim diabetes-related visits between groups would have enhanced the internal validity of the studies.

Two studies[27,31] did not report the actual number of telephone calls patients received during the intervention period. Glasgow and Toobert[24] reported an implementation score of 80% to 90% for calls scheduled 3 to 4 per individual over 6 months. The remaining studies reported an average of 16 calls per participant over a 3-month intervention,[25,26,28] an average of 6 calls per participant over 12 months,[30] and an average of 13 calls per participant over 12 months.[29] The variation in both the intensity and reporting of intensity of the interventions makes it difficult to draw conclusions on the basis of this variable. It remains unclear what intensity of telephone intervention is most likely to impact glycemic control.

External validity

The generalizability of this body of literature is limited to patients with type 2 DM who have similar characteristics to the participants who were studied and who are receiving care in similar settings. This is largely because only 1 study used random selection of participants. Random selection of participants is the only method that can theoretically ensure representation of the true population from which the sample was drawn.[33]

CONCLUSION

The Diabetes Control and Complications Trial[34] reported that the costs associated with an expert team of clinicians working with patients in the intensive therapy group were considerable ($4000 per year intensive therapy versus $1666 per year conventional therapy).[35] Because needed resources are not always available in the general community, new strategies that require less cost and effort to maintain this level of intensive therapy are needed.[34] The UKPDS[6] confirmed the findings of the Diabetes Control and Complications Trial in patients with type 2 DM. Previous research has shown that self-management training and disease management programs are effective in achieving glycemic control in patients with type 2 DM, but that knowledge regarding the effects of individual management strategies is limited.[36]

This review attempts to clarify the effects of telephone interventions on glycemic control in type 2 DM to inform the practice of providers considering using this approach. Only studies that examined the effect of telephone interventions without requiring participants to connect to the Internet were included. However, 3 of the studies used advanced technology to deliver the intervention.[29–31] Limitations of this review include a narrow search strategy that may have contributed to the small number of articles reviewed. No attempt was made to review unpublished works. Glycemic control was not the primary outcome of interest in all of the studies reviewed, which might have limited the power these studies had to detect changes in glycemic control. No attempt was made in this review to examine the potential mediating effect that changes in self-care behavior or other factors may have had on glycemic control, which limits the ability to understand the effects of these factors on glycemic control.

Although current evidence does not support the use of telephone interventions to improve glycemic control in type 2 DM, well-designed studies to establish the effectiveness of this potentially cost-effective modality can be an important step in addressing the diabetes epidemic. Future studies should evaluate the effects of advanced technology such as automated systems that deliver messages and collect information, cell phones, and video messaging.

REFERENCES

1. American Diabetes Association. Total prevalence of diabetes & pre-diabetes. http://www.diabetes.org/diabetes-statistics/prevalence.jsp. Accessed July 18, 2008.
2. Centers for Disease Control and Prevention. National diabetes fact sheet United States 2005. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2005.pdf. Accessed July 18, 2008.
3. National Institute of Diabetes and Digestive and Kidney Diseases. National diabetes statistics, 2007. http://diabetes.niddk.nih.gov/dm/pubs/statistics. Published 2008. Accessed July 15, 2008.
4. Wright A, Burden ACF, Paisey RB, Cull CA, Holman RR. Sulfonylurea inadequacy: efficacy of addition of insulin over 6 years in patients with type 2 diabetes in the U.K. Prospective Diabetes Study (UKPDS 57). *Diabetes Care.* 2002;25:330–336.
5. Stratton IM, Adler AI, Neil AW. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ.* 2000;12:405–412.
6. United Kingdom Prospective Diabetes Study (UKPDS). Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet.* 1998;352:837–853.
7. Koro CE, Bowlin SJ, Bourgeois N, Fedder DO. Glycemic control from 1988 to 2000 among US adults diagnosed with type 2 diabetes: a preliminary report. *Diabetes Care.* 2004;27:17–20.
8. Harris MI. Health care and health status and outcomes for patients with type 2 diabetes. *Diabetes Care.* 2000;23:754–758.
9. Tucker C, Brick JM, Meekins B. Household telephone service and usage patterns in the United States in 2004: implications for telephone samples. *Public Opin Q.* 2007;17:3–22.

10. Friedman RH, Kazis LE, Jette A, et al. A telecommunications system for monitoring and counseling patients with hypertension: impact on medication adherence and blood pressure control. *Am J Hypertens.* 1996;9:285–292.
11. Follick MH, Gorkin L, Smith TW, Capone RJ, Visco J, Stablein D. Quality of life post–myocardial infarction: effects of a transtelephonic coronary intervention system. *Health Psychol.* 1988;7:169–182.
12. Eakin S, Lawler C, Vandelanotte N, Owen N. Telephone interventions for physical activity and dietary behavior change: a systematic review. *Am J Prev Med.* 2007;32:419–434.
13. Riegel B, Carlson B, Kopp Z, LePetri B, Unger A, Glaser D. Effect of a standardized nurse case management telephone intervention on resource use in chronic heart failure patients. *Arch Intern Med.* 2002;162:705–712.
14. American Association of Diabetes Educators (AADE). Intensive diabetes management: implications of the DCCT and UKPDS. *Diabetes Educ.* 2002;28:735–740.
15. Moore PA, Zgibor JC, Dasanayake AP. Diabetes: a growing epidemic of all ages. *J Am Dent Assoc.* 2003;134(suppl):11–15.
16. Wu L, Forbes A, Griffiths PD, While A. Telephone follow-up for type 2 diabetes mellitus (Protocol). *Cochrane Database Syst Rev.* 2009;1:1–27. http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD006694/pdf_fs.html.
17. Upadhyay N, Kokalj Kokot M, Kokalj Kokot M, Car J, Svab I. Mobile phone messaging—a telemedicine for people with diabetes mellitus (Protocol). *Cochrane Database Syst Rev.* 2009;1:1–21. http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD006393/pdf_fs.html.
18. Vermeire E, Wens J, Van Royen P, Biot Y, Hearnshaw H, Lindenmeyer A. Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev.* 2005:2. Art. No.: CD003638. doi:10.1002/14651858.CD003638.pub2.
19. Renders CM, Valk GD, Griffin S, Wagner EH, van Eijk JThM, Assendelft WJJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev.* 2000:4. Art. No.: CD001481. doi:10.1002/14651858.CD001481.
20. Day JC, Janus A, Davis J. *Computer and Internet Use in the United States: 2003.* Washington, DC: US Department of Commerce. Economics and Statistics Administration. US Census Bureau; 2005:1–14.
21. Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions. The Cochrane Collaboration 2008. http://www.cochrane-handbook.org/. Accessed July 18, 2008.
22. American Diabetes Association (ADA). Standards of medical care in diabetes-2007. *Diabetes Care.* 2007;30(suppl 1):S4–S41.
23. Garrard J. *Health Sciences Literature Review Made Easy: The Matrix Method.* Sudbury, MA: Jones and Bartlett; 2004.
24. Glasgow RE, Toobert DJ. Brief, computer-assisted diabetes dietary self-management counseling. *Med Care.* 2000;38:1062–1073.
25. Kim H, Oh J. Adherence to diabetes control recommendations: impact of nurse telephone calls. *J Adv Nurs.* 2003;44:256–261.
26. Kim H, Oh J, Lee H. Effects of nurse-coordinated intervention on patients with type 2 diabetes in Korea. *J Nurs Care Qual.* 2005;20:154–160.
27. Maljanian R, Grey N, Staff I, Conroy L. Intensive telephone follow-up to a hospital-based disease management model for patients with diabetes mellitus. *Dis Manag.* 2005;8:15–25.
28. Oh J, Kim H, Yoon K, Choi E. A telephone-delivered intervention to improve glycemic control in type 2 diabetic patients. *Yonsei Med J.* 2003;44:1–8.
29. Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a department of Veteran's Affairs health care system. *Diabetes Care.* 2001;24:202–208.
30. Piette JD, Weinberger M, McPhee SJ, Mah CA, Kraemer FB, Crapo LM. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes? *Am J Med.* 2000;108:20–27.
31. Young RJ, Taylor J, Friede T, et al. Pro-active call center treatment support (PACCTS) to improve glucose control in type 2 diabetes. *Diabetes Care.* 2005;18:278–282.
32. Schulz KF, Grimes DA. Allocation concealment in randomized trials: defending against deciphering. *Lancet.* 2002;359:614–618.
33. Burns N, Grove SK. *The Practice of Nursing Research: Appraisal, Synthesis, and Generation of Evidence.* 6th ed. St Louis, MO: Saunders; 2009.
34. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329:977–986.
35. Resource utilization and costs of care in the diabetes control and complications trial. *Diabetes Care.* 1995;18:1468–1478.
36. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes. *Diabetes Care*. 2001;24:561–587.